



Mailed: April 1, 2002

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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,933,456

CORRECTED NOTICE OF FINAL DETERMINATION

This notice replaces the notice mailed January 2, 2002. A determination has been made that U.S. Patent No. 4,933,456, which claims the human drug product TESLASCAN®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,628 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. In the absence of such request for reconsideration or document evidencing the change of name, the Director will issue a certificate of extension, under seal, for a period of 1,765 days to Amersham Health Salutar, Inc..

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of January 31, 2000 (65 Fed. Reg. 4615). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,325 - 403) + 804 \\ &= 1,765 \text{ days (4.8 years)}\end{aligned}$$

Since the regulatory review period began May 5, 1989, before the patent issue date (June 12, 1990), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 5, 1989 to June 12, 1990 is 403 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,765 days, would extend the patent from June 12, 2007 (35 U.S.C. § 154) to April 11, 2012, which is beyond the 14-year limit (the approval date is November 26, 1997, thus the 14 year limit is November 26, 2011). The period of extension is thus limited to November 26, 2011, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, June 12, 2007, to and including November 26, 2011, or 1628 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the

Official Gazette:

U.S. Patent No.	:	4,933,456
Granted	:	June 12, 1990
Original Expiration Date	:	June 12, 2007
Applicant	:	Scott M. Rocklage, et al.
Owner of Record	:	Amersham Health Salutar, Inc.
Title	:	Dipyridoxyl Phosphate NMRI Contrast Agents
Classification	:	546/5
Product Trade Name	:	TESLASCAN®
Term Extended	:	1,628 days
Expiration Date of Extension	:	November 26, 2011

Any correspondence with respect to this matter should preferably be faxed to:

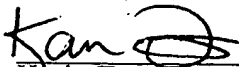
FAX: (703) 872-9411

Alternatively, correspondence sent by mail should be directed to:

Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231; **or, preferably**

U.S. Patent and Trademark Office, Box Patent Ext.
P.O. Box 2327
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
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RE: TESLASCAN®
FDA Docket No.: 98E-0479